REMARKS

Claims 1-15 and 17-28 are pending in the instant specification. Applicants have amended claims 1, 2 and 26. Support for these amendments can be found, for example, page 4, lines 18-20 and page 10, lines 21-22 of the instant specification. No new matter is added.

Request for Withdrawal of Finality

Applicants request withdrawal of finality of the Office Action. In order for claims subject to an RCE to be finally rejected on the first Office action, the claims must be drawn to the same invention claimed before entry of the submission under 37 C.F.R. § 1.114 and would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to the filing of the RCE under 37 CFR § 1.114.[1] A second Office action may not be properly made final when the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 C.F.R. § 1.97(c) with the fee set forth in 37 C.F.R. § 1.17(p). The Examiner provided a new ground for rejection on page 6, paragraph 7 of the Office Action *i.e.* anticipation of claims 25-28 by Hoerstrup. This rejection was not made in the previous Office Action, nor was it necessitated by Applicants' amendment. Further, No IDS has been filed. Withdrawal of the finality of this Office Action is requested.

Claim Rejections

35 U.S.C. § 103

The Examiner has maintained the rejection of claims 1-15 and 18-28, on pages 2-6 of the Office Action, under 35 U.S.C. § 103 for being obvious over Hoerstrup DE19919625 ("Hoerstrup"). The Examiner argued that the "suture ring" of claims 1-15 and 18-28 is obvious because it is known to be an element of heart valves.[2] Further, the Examiner argued that the use of "biodegradable" and "poorly degradable" in the claims was non-limiting because both types

[1] *See* MPEP § 706.07(b).
[2] *See* the Office Action at page 2, paragraph 1.

of material could be made from PHA.[3] Applicants respectfully traverse the rejection for the reasons below.

Applicants have amended claims 1, 2 and 26 to specify that the biodegradable material begins degrading at least 8 days after colonizing the device with cells and completes degradation by, at most, 3 months. The Applicants have amended claims 1, 2 and 26 to further specify that the poorly degradable material does not degrade for longer than a year after colonizing the device with cells. Thus, despite the possibility that PHA could be used, at least in part, to construct either material, the amount of PHA used and the other components that PHA is combined with differentiate a biodegradable material from a poorly degradable material.

Hoerstrup does not teach the use of a non-degradable or poorly degradable frame construction. The Examiner has not explained why claims 1-15 and 18-28 are obviousness despite the lack of this teaching in Hoerstrup. The Examiner has only alleged that because the inner structure of the device and the frame of claims 1-15 and 18-28 could be made of the same material that it is obvious over the teachings of Hoerstrup. Applicants submit that the inner structure and frame cannot be made from the same material because of the distinct properties of the inner structure and the frame. Thus, Applicants submit that the Examiner has not made a *prima facie* case of obviousness of claims 1-15 and 18-28 over the teachings of Hoerstrup.

The Examiner further cited Ionescu, U.S. Patent No. 4,441,216 ("Ionescu"), Penny, U.S. Patent No. 4,816,029 ("Penny") and Rosen, U.S. Patent No. 4,345,340 ("Rosen") for examples of stented heart valves. The devices of claims 1-15 and 18-28 are also distinct from the teachings of these references. None of the devices taught in Ionescu, Penny or Rosen have any biodegradable or even non-degradable parts.

The Examiner has also rejected claim 17, on page 6 of the Office Action, under 35 U.S.C. § 103 for being obvious over Hoerstrup DE19919625 ("Hoerstrup") in light of Rosen, U.S. Patent No. 4,627,879 ("Rosen"). The Examiner argued that Hoerstrup teaches all of the limitations of claim 17 except it does not teach the use of a fibrin glue. The Examiner cites that Rose teaches the use of fibrin glue. Further, the Examiner argued that the use of "biodegradable" and "poorly degradable" in the claims was non-limiting because both types of material could be

[3] *Id.* at page 3.

made from PHA.[4] Applicants respectfully traverse the rejection for the same reasons described for the rejection of claims 1-15 and 18-28, above.

For all of the above reasons, Applicants submit that no *prima facie* case of obviousness has been established by the Examiner and respectfully request that these rejections be withdrawn.

35 U.S.C. § 102

The Examiner also has rejected claims 25-28, under 35 U.S.C. § 102 for being anticipated by the teachings of Hoerstrup. The Examiner argued that the heart valve described by Hoerstrup could be constructed by the procedure of claims 1 or 2 and that the valve of claim 26 is encompassed by the teachings of Hoerstrup. Applicants respectfully disagree.

Applicants assert that Hoerstrup does not teach each and every limitation of the heart valves of claims 25-28. Specifically, Hoerstrup does not teach a heart valve with a biodegradable inner structure and a non-degradable or slowly degradable frame. Thus, Applicants submit that Hoerstrup cannot anticipate claims 25-28 and respectfully request that this rejection be withdrawn.

[4] *Id.* at page 3.

CONCLUSION

A favorable action on the merits is respectfully requested. If further discussion of this case is deemed helpful, the Examiner is encouraged to contact the undersigned at the telephone number provided below, and is assured of full cooperation in progressing the instant claims to allowance.

Respectfully submitted,

/Sean M. Coughlin/
Ivor R. Elrifi, Reg. No. 39,529
Sean M. Coughlin, Reg. No. 48,593
Attorneys for Applicants
c/o MINTZ LEVIN
Tel: (202) 585-3577
Fax: (617) 542-2241
Customer No. 30623

Dated: July 29, 2009

ACTIVE 4672573v.1